



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-441/S-001

Wyeth Consumer Healthcare
Attention: Lauren Quinn
Associate Director, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Quinn:

Please refer to your supplemental new drug application dated December 30, 2003, received December 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Allergy Sinus Caplets (200 mg ibuprofen, 30 mg pseudoephedrine HCl, and 2 mg chlorpheniramine maleate tablets).

We acknowledge receipt of your submissions dated April 30 and July 7, 2004. Your submission of April 30, 2004 constituted a complete response to our March 4, 2004 action letter.

This supplemental new drug application proposes the additional tradename Advil Multi-Symptom Cold for the product.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (container label submitted December 30, 2003, and carton label submitted April 30, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-441/S-001." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated July 7, 2004. This commitment is listed below.

1. A study adequately designed to assess consumer comprehension of the similarities and differences between this product and Advil Allergy Sinus Caplets (also marketed under this NDA), and to identify labeling that will provide optimal consumer comprehension of the ingredients and uses for these two products.

Protocol Submission: by June 2005
Study Start: by October 2005
Final Report Submission: by March 2006

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **“Postmarketing Study Protocol”, “Postmarketing Study Final Report”, or “Postmarketing Study Correspondence.”**

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Leah Cutter, Ph.D., Regulatory Project Manager, at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Charles Ganley
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